K010196

APR - 5 2001

SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Trade Name: **TOTAL CURE- Oxygen Barrier**
Common Name: **Tooth Shade Resin Material (Accessory)**

Classification Name: **Tooth Shade Resin Material**
21 CFR 872.3690, Class II

Description of Applicant Device:
TOTAL CURE is a water-based, semi-gel, oxygen barrier solution.

Intended Uses of Applicant Device:
TOTAL CURE is designed to eliminate the oxygen-inhibited layer upon polymerization of the composite. It produces a shiny surface reducing the need for polishing procedures.

Predicate Device:
K941065 DEOX®, OXYGEN BARRIER VISCOUS SOLUTION

Significant Performance Characteristics:

	TOTAL CURE	DEOX®
INTENDED USE:	Designed to prevent oxygen inhibition layer formation on the surface of resin materials when they are polymerized to attain a smooth, shiny finish on the surface of the filling.	Designed to prevent oxygen inhibition layer formation on the surface of resin materials when they are polymerized.
PRODUCT DESCRIPTION:	Blue, water-based, semi-gel solution	Clear, viscous, glycerin-based solution
DELIVERY SYSTEM:	Single Use, low density PE container with easily controlled tip.	Syringe/tip

Side by side comparisons of TOTAL CURE to the predicate device DEOX® clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device.

It is concluded that the information supplied in this submission has proven the safety and efficacy of TOTAL CURE.

Cyndy Oris
Manager, Regulatory Affairs
1-800-BIS-DENT or 847-534-6146
Fax: 847-534-6396

January 18, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Ms. Cyndy Oris
Regulatory affairs Manager
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K010196
Trade Name: Total Cure
Regulatory Class: II
Product Code: EBF
Dated: January 18, 2001
Received: January 22, 2001

Dear Ms. Oris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Submission for TOTAL CURE
BISCO, INC., 1100 W. Irving Park Road
Schaumburg, IL. 60193

Indications for Use

510(k) Number (if known): K010196

Device Name: TOTAL CURE

Indications for Use: A water-based, semi-gel solution designed to eliminate the oxygen-inhibited layer upon polymerization of the composite.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ ___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K010196